K013344

Philips Medical Systems

P.O. Box 10000, 5680 DA Best, The Netherlands

XJB148-4709/bf
2001-09-18

DEC 1 1 2001

510(k) SUMMARY

The following information is being submitted in accordance with the requirements of 21 CFR 807.92.

Company Name	:	Philips Medical Systems North America Company.
Address	:	472 Wheelers Farms Road Milford, CT 06460.
Registration No.	:	1217116
Contact person	:	Peter Altman
Device (Trade) Name	:	**INTERA I/T**
Classification Name	:	Magnetic Resonance Diagnostic Device (MRDD).
Classification	:	Class II.
Product code	:	LNH
Performance standards	:	NEMA voluntary standards, FDA MRDD guidance's, UL and IEC 60601 appropriate safety standards and/or draft standards are used.
Common/Usual Name	:	**INTERA I/T**.

Predicate Device(s).

The Philips cleared MRDD Philips INTERA 1.5T system with FDA ref.K001796.

Intended Use.

INTERA I/T is a whole body 1.5T Magnetic Resonance Diagnostic Device extended with optional hardware extensions to aid in the performance of interventional procedures in the head, body and extremities, which may be facilitated by MR techniques, such as real time imaging. Such procedures must be performed with MR compatible instrumentation as selected and evaluated by the clinical user.

Device Description and Technological Characteristics

The INTERA I/T is based on the same platform as Philips INTERA 1.5T system (predicate device) with the same intended use but extended with additional hardware features. The optional hardware extensions are meant to aid in the performance of interventional procedures in the head, body and extremities, which may be assisted by existing MR techniques, such as real time imaging.
The extension provides the facility to transfer the patient including the patient tabletop from a diagnostic imaging device of other modality (workspot), e.g. X-ray, to the MR system vice-versa. These additional workspots are located outside the 0.5mT-fringe field of the MR system.

The **INTERA I/T** will be offered in three optional versions

INTERA I/T Standard.

The standard version is meant to aid the performance of interventional procedures, which do not require transfer of the patient from another workspot, such as an another imaging device, to the MR system and vice-versa.

INTERA I/T Neurosurgery.

The Neurosurgery version is meant to aid the performance of interventional procedures in the head/neck area. The patient can be transferred from a workspot outside the 0.5 mT fringe field area to the MR system and vice-versa.

INTERA I/T CV.

The CV version is meant to aid the physician in the performance of interventional procedures focus to cardiovascular. The patient can be transferred from a workspot outside the 0.5 mT fringe field area to the MR system and vice-versa.

The hardware extensions comprises of:

- **Adaptation of the standard MR patient support system.**
  For the INTERA I/T systems the MR patient support (table) is provided with a mechanical docking system to facilitate the transfer of the tabletop to the additional table and vice-versa. The length of the MR tabletop has been extended with 8 cm compared to the INTERA 1.5T system..
- **Additional Patient Table (workspot outside the 0.5 mT fringefield).**
  A workspot is loacated outside the 0.5 mT fringefield. The additional (optional) Patient Table is meant to transfer the patient from the MR system to another workspot and vice-versa.. There are two types of additional patient tables:
  - Stationary Pivot version on which the tabletop can be rotated over 0 – 180 degrees.
  - Extended Table Track on rails to allow inline transportation of the tabletop over an additional distance of approximately 2-meter.
- Interactive Display with a rail ceiling suspension. The interactive display is provided with a second LCD display with standardized video signal input (connection)
- Interventional received RF-coils: Synergy Flex (circular) Large, Medium and Rectangular.
- Additional accessories: Head tilting device (Trendelenburg positioning possibility), straps and an add-on table top extension.

Safety parameters.

The safety parameters of the INTERA I/T remains the same as with its predicate device INTERA 1.5T (ref.K0001796).

General Safety and Effectiveness.

The safety and effectiveness of the INTERA I/T are the same with its predicate device the INTERA 1.5T (ref K001796.). It does not induce other safety issues and warnings than already valid for its predecessor and predicate device.

Substantial Equivalence.

The INTERA I/T is substantially equivalent to the predicate device Philips INTERA 1.5T with FDA ref. K001796.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 1 2001

Mr. Peter Altman
Director of Regulatory Affairs
Philips Medical Systems
North America Company
472 Wheelers Farm Road
P.O. Box 3828
MILFORD CT 06460

Re: K013344
Trade/Device Name: INTERA I/T MR System
MRI System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 LNH
Dated: October 5, 2001
Received: October 9, 2001

Dear Mr. Altman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Philips Medical Systems

P.O. Box 10000, 5680 DA Best, The Netherlands

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510(k) Number (if known): K013344
Device Name : **INTERA I/T**

Indication For Use :

INTERA I/T is a whole body 1.5T Magnetic Resonance Diagnostic Device being extended with optional hardware extensions to aid in the performance of interventional procedures in the head, body and extremities, which may be facilitated by MR techniques, such as real time imaging.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013344